TESTIMONY OF SCOTT BASS, SIDLEY & AUSTIN

ON BEHALF OF

THE NATIONAL NUTRITIONAL FOODS ASSOCIATION

FOOD & DRUG ADMINISTRATION
PUBLIC MEETING ON IMPLEMENTING
THE *PEARSON* COURT DECISION
AND OTHER HEALTH CLAIMS ISSUES

DEPARTMENT OF EDUCATION AUDITORIUM
400 MARYLAND AVENUE, S.W.
WASHINGTON, D.C.
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Thank you for requesting the input of the National Nutritional Foods Association. NNFA is the largest and oldest trade association in the world representing thousands of natural products retailers, distributors and manufacturers. NNFA has been active in governmental proceedings affecting dietary supplement and other products for over 60 years. I am a partner in the Washington, D.C. office of Sidley & Austin, General Counsel for NNFA.

NNFA has been asked to deal with the questions of how to phrase qualifying language for health claims and whether additional information is necessary to assist consumers with health claims. Before answering those questions we must touch upon the issues posed to Panels I and III, starting most logically with the latter.

At bottom, NNFA believes in the integrity of the product category system established in the Federal Food, Drug, and Cosmetic Act. It believes that some products are so severe in effect and carry such high risk in relation to their potential high benefit, that they need careful FDA review. In short, NNFA believes that this country does need a drug approval system. We note that this was reflected in the negotiations that led to DSHEA: Sections 201(ff)(3) and 403(r)(6) explicitly separate dietary supplements from drugs.

Pearson, taken to its logical extreme, could be misread to permit *any* claim to be made with appropriate qualifiers. [1] NNFA strongly opposes any such reading or implementation of that decision.

[1] The following is not the type of disclaimer that NNFA believes should be permissible: "This product may cure liver cancer. There have been two animal tests thus far, neither on species demonstrated to be applicable to humans. Clinical studies would be necessary before applying this evidence."

NNFA does wish to note that there may be other drug categories, such as traditional herbal medicines, for which it would not be appropriate to impose pre-market approval regimens, but, once again, NNFA acknowledges that greater controls are necessary than in the food/dietary supplement area.

Assuming, then, that there *should be* health claims, and not just one category of therapeutic/health claim with endless qualifiers, the question is what is the appropriate standard and what type of disclaimers may be made that are consistent with that standard.

NNFA believes that the "significant scientific agreement" standard was too rigidly applied by FDA and is still the subject of too much confusion. In the dietary supplement context, we note that the reason that Section 403(r)(5)(D) was drafted was precisely to permit FDA to incorporate rapidly advancing science into the health claims approval process and adapt to this new marketplace. FDA's failure to implement that newer standard in proposed regulations in late 1991 actually spawned the DSHEA effort.

DSHEA and *Pearson* alter the FDA claims review standard. NNFA believes that the significant scientific agreement standard should operate in practice more like the manner in which GRAS panels operate. There is give-and-take, there is consideration of alternatives, and there is very careful consideration of the advancing state of science. What NNFA believes should not occur is the rigidity which the old food additives standard was applied as a safety measure to dietary supplements.

Moving on to disclaimers, *Pearson* says that disclaimers are preferable to suppression. NNFA agrees. That case also says that FDA can ban claims when the evidence against the claims outweighs the evidence in favor of the claims. NNFA wants to see consumers protected.

A key portion of adequate substantiation is the consideration of safety. The higher the risk, the stronger the disclaimer needs to be. A good example of strong disclaimers are the warnings that responsible companies adopted on ephedra labels.

NNFA believes that qualifying language should be very short. It should be very pointed. The warning should be phrased in a way that product liability warnings are phrased by experts who drafts such warnings. Phrases such as "animal studies only; not tested on humans;" "limited number of human trials; efficacy not fully established;" and/or "not proven in humans" are examples of such strong language.

NNFA believes that disclaimers should be in proximity to the principal claim and should appear wherever that claim appears on labels, labeling or advertising.

On the other hand, NNFA does not believe that FDA should require disclaimers for every type of health claim. It is only where the science falls short of a reasonable "significant scientific agreement" standard (or where safety issues so mandate) that a disclaimer should be required.

NNFA does believe that there should be additional information provided by FDA through publicity and through consumer booklets and websites information. One area that would be very helpful would be category–specific information in addition to general information on what disclaimers mean. NNFA does not believe that consumers will absorb general rules about health claims and disclaimers, but will focus upon the names of the products that they intend to purchase. Needless to say, NNFA believes that the information provided to consumers should not be negative about a product or product category but rather informative.

CONCLUSION

NNFA believes that the majority of the dietary supplement/natural products industry is responsible and desires proper guidelines. The interests of the consumer are paramount and, while there is some inherent risk in promoting the benefits of healthful products, that risk is far lower for dietary supplements than it is for prescription drugs.

Congress made a definitive statement when it created the new dietary supplement category in DSHEA. It also left the drug category intact. NNFA believes that *Pearson* should be implemented in a fashion that gives full meaning to Judge Silberman's decision while at the same time retaining the safety underpinnings of the "drug" versus non-drug categorization in the Federal Food, Drug, and Cosmetic Act.

In assessing the viability of disclaimers on health claims, that effort should not extend beyond health claims as such. Assuming that the bright line dividing health claims from structure/function claims is the mention of disease, and assuming that health claims are primarily claims for the prevention of long-term or chronic disease conditions, disclaimers can be fashioned in simple, strong language that inform the consumer and permit an expanded array of claims.